510 (K) SUMMARY

Prepared:	August 29, 2005
Submitter:	Serim Research Corporation
Address	P.O. Box 4002 Elkhart IN 46514
Phone: **Fax:**	574-264-3440 574-266-6222
Contact:	Patricia A. Rupchock Manager of Regulatory Affairs
Device Trade Name:	The Serim® Peracetic Acid Chemical Indicator
Common or Usual Name:	Chemical Indicator
Device Classification Name:	Indicator, Physical/Chemical Sterilization Process
Product Code:	JOJ
Class:	II
Regulation Number:	880.2800
Substantial Equivalence:	The Serim® Peracetic Acid Chemical Indicator is substantially equivalent to STERIS PROCESS™ Chemical Monitoring Strips[1] (K921559, February 28, 1995)
Device Description:	The device is a qualitative, single use, reagent test strip made up of a 0.20 inch square purple reagent pad that has been chemically treated to detect the active ingredient in the Steris 20 ™ Sterilant[2] when used in the STERIS SYSTEM 1® Processor[3]. The pad is affixed to one end of a 3.25 inch by 0.20 inch white opaque polystyrene strip.

[1] STERIS PROCESS is a trademark of the Steris Corporation
[2] Steris 20 is a trademark of the Steris Corporation
[3] STERIS SYSTEM 1 is a registered trademark of the Steris Corporation

Intended Use:

The Serim ® Peracetic Acid Chemical Indicator test strips are designed for use in a STERIS SYSTEM 1® Processor with STERIS 20™ Sterilant to detect peracetic acid concentration in the use solution.

Technological Characteristics:

The Serim® Peracetic Acid Chemical Indicator is identical to the STERIS PROCESS™Chemical Monitoring strip (manufactured by Serim Research Corp. for Steris Corporation) that has been previously cleared by the FDA (K921559).

The STERIS PROCESS™Chemical Monitoring Strip was developed by Serim Research Corporation and has been exclusively manufactured by Serim Research Corporation since the product was introduced. The Serim® Peracetic Acid Chemical Indicator will be used for the independent monitoring of the STERIS SYSTEM 1® employing STERIS 20™ Sterilant. The Serim® Peracetic Acid Chemical Indicator is a qualitative, single use, chemical indicator used to detect the active ingredient of the STERIS 20™ Sterilant.

The Serim® Peracetic Acid Chemical Indicator is configured as a paper pad on a plastic strip support. A dye in the chemical indicator pad is oxidized (bleached) by the use solution. The extent of bleaching indicates whether a sufficient concentration active agent (peracetic acid) was present. At the end of the processing cycle the user compares the reacted indicator to a color chart composed of two color blocks. The "START" color block is similar to the unreacted indicator strip. The "COMPLETE" color block is similar to an indicator strip that has been exposed to peracetic acid at or above a concentration of 1500 ppm.

Performance and Conclusion:

Serim Research Corporation hereby certifies that it developed the product known as the STERIS PROCESS™ Chemical Monitoring strip prior to the FDA 510(k) clearance of this product. Serim Research Corporation also has manufactured this material since the introduction of this product. The role of Serim Research Corporation in the development and manufacture of the product is acknowledged on the bottle label of the STERIS PROCESS™ Chemical Monitoring Strip

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2005

Ms. Patricia A. Rupchock
Manager of Regulatory Affairs
Serim Research Corporation
23565 Reedy Drive
Elkhart, Indiana 46514

Re: K052388
Trade/Device Name: Serim® Peracetic Acid Chemical Indicator
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: November 14, 2005
Received: November 18, 2005

Dear Ms. Rupchock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

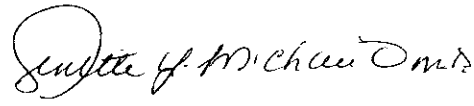
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K052388

Device Name: Serim® Peracetic Acid Chemical Indicator

Indications For Use:

The Serim ® Peracetic Acid Chemical Indicator test strips are designed for use in a STERIS SYSTEM 1® Processor with STERIS 20™ Sterilant to detect peracetic acid concentration in the use solution.

Prescription Use _____ AND / OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

11/30/05

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K052388